UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND
NORTHERN DIVISION

JULIA BROOKS **Plaintiff,** **-versus-** **BIOMET, INC., BIOMET ORTHOPEDICS, LLC, BIOMET U.S. RECONSTRUCTION, LLC, and BIOMET MANUFACTURING, LLC** **Defendants.**	**Civil Action No.** **COMPLAINT FOR DAMAGES** **JURY TRIAL DEMANDED**

Plaintiff, Julia Brooks ("Plaintiff") residing in Cambridge, County of Dorchester, State of Maryland, by way of Complaint against Defendants; BIOMET, INC.; BIOMET ORTHOPEDICS, LLC; BIOMET U.S. RECONSTRUCTION, LLC; and BIOMET MANUFACTURING, LLC (hereafter collectively referred to as "Biomet" or "Biomet Defendants" or "Defendants").

PARTIES, VENUE AND JURISDICTION

1. This is a lawsuit regarding a defective metal-on-metal hip replacement system implanted in Plaintiff, Julia Brooks, which was designed, developed, manufactured, labelled, promoted, marketed, sold, and supplied by Defendants.
2. The particular hip replacement system at issue in this case is the "Biomet M2a Metal on Metal Hip Replacement" (hereafter referred to as the "M2a").
3. Julia Brooks was implanted with the Biomet M2a Magnum metal-on-metal hip replacement in the State of Maryland.
4. At the time the M2a caused Julia Brooks injury, she was a resident of Maryland. She

underwent revision surgery of the M2a city of Germantown, County of Montgomery, State of Maryland.

5. At all times relevant to this Complaint, Defendant BIOMET, INC., was and is an Indiana-based multinational corporation, with its corporate headquarters in Warsaw, Indiana and facilities world-wide.

6. Defendant, BIOMET ORTHOPEDICS, LLC is a limited liability company organized and existing under the laws of Indiana with its principal place of business in Warsaw, Indiana. The sole member of BIOMET ORTHOPEDICS, LLC is BIOMET U.S. RECONSTRUCTION, LLC., which is incorporated in Indiana and has its principal place of business in Warsaw, Indiana.

7. At all relevant times, BIOMET ORTHOPEDICS LLC designed, manufactured, marketed, promoted, sold and introduced into interstate commerce, either directly or indirectly, the Biomet Hip Systems that are the subjects of this lawsuit.

8. Defendant, BIOMET ORTHOPEDICS, LLC is a limited liability company organized and existing under the laws of Indiana with its principal place of business in Warsaw, Indiana. The sole member of BIOMET ORTHOPEDICS, LLC is BIOMET U.S. RECONSTRUCTION, LLC., which is incorporated in Indiana and has its principal place of business in Warsaw, Indiana.

9. At all relevant times, BIOMET ORTHOPEDICS LLC designed, manufactured, marketed, promoted, sold and introduced into interstate commerce, either directly or indirectly, the Biomet Hip Systems that are the subjects of this lawsuit.

10. BIOMET MANUFACTURING, LLC, f/k/a BIOMET MANUFACTURING CORP. is a limited liability company organized and existing under the laws of Indiana with its principal

place of business in Warsaw, Indiana. The sole member of BIOMET MANUFACTURING, LLC is Chad F. Phipps., who is domiciled in Indiana.

11. Defendant BIOMET MANUFACTURING, LLC, f/k/a BIOMET MANUFACTURING CORP. designed, manufactured, marketed, promoted, and sold the Device that was implanted into Plaintiff's body and is the subject of this action.

12. At all times relevant herein, the Biomet Defendants were the agents of each other, and in doing the things alleged herein, each Defendant was acting within the course and scope of its agency and was subject to and under the supervision of each and every other Defendant herein. Specifically, each Defendant was but an instrumentality or conduit of the other in the prosecution of a single venture, namely the design, manufacture, promotion and sale of the M2a-Magnum Hip System and the M2a Magnum System. Therefore, it would be inequitable for either Defendant to escape liability for any obligation of the other.

13. In June of 2015, BIOMET, INC, was purchased by ZIMMER BIOMET HOLDINGS, INC., also having its world-wide corporate headquarters in Warsaw, Indiana. In June of 2015, Biomet Orthopedics, LLC, Biomet U.S. Reconstruction, LLC, and Biomet Manufacturing, LLC were wholly owned subsidiaries of Biomet, Inc. In June of 2015, the parent company of BIOMET, INC, LVB ACQUISITION, Inc., was purchased by ZIMMER HOLDINGS, INC, which also had its world-wide corporate headquarters in Warsaw, Indiana. The 2014 Annual Report issued by Zimmer Holdings, Inc. indicated that "on April 24, 2014, we entered into a definitive agreement to merge with LVB Acquisition, Inc., the parent company of Biomet, Inc. in a cash and stock transaction valued at approximately $13.35 billion . . . . . In connection with the Biomet merger, we will pay off all of LVB's outstanding funded debt . . . The merger will position the combined company

as a leader in the $45 billion musculoskeletal industry." The 2014 Annual Report also infers that after the merger, the activities of Biomet, Inc. would be synergized with those of Zimmer Holdings, Inc. (including Zimmer, Inc.). Simultaneous with the June 2015 merger, Zimmer Holdings, Inc. changed its name to Zimmer Biomet Holdings, Inc. and thereafter, subsidiaries of the new Zimmer Biomet Holdings, Inc. took on the trade name and began doing business as "Zimmer Biomet." According to the 2015 Annual Report, by the last half of 2015 significant progress at integration of Biomet, Inc. and Zimmer Biomet Holding, Inc. had been accomplished by integrating global sales leaders, operating synergies, products, research and development. The 2015 Annual report indicates that Zimmer Biomet Holdings, Inc.'s sales had increased by 28.3 percent due to the merger. In a 2016 response to the FDA, David Kunz, Senior Vice President, Global Quality, Regulatory & Clinical Affairs for Zimmer Biomet Holdings, Inc. told the FDA that after the merger was closed, Zimmer Biomet Corporate directed corporate quality audits, initiated a remediation program at the Warsaw North Campus (Biomet facility) and implemented Zimmer Biomet quality standards for the network as part of the Quality Excellence Plan. Based on the public statements of Zimmer Biomet Holdings, Inc., from June 2015 to present, all activities of the subsidiary companies relating to the product at issue in this case were directed and controlled by ZIMMER BIOMET HOLDINGS, INC. In Biomet's words, "Biomet is now Zimmer Biomet."[1]

14. Jurisdiction is proper in the courts of the State of Maryland because Plaintiff is a citizen of Maryland, all Defendants marketed, sold, and distributed the M2a product line in

[1] *See*, legacy Biomet homepage at: http://www.biomet.com/wps/portal/internet/globalLocations/!ut/p/a1/04_Sj9CPykssy0xPLMnMz0vMAfGjzOL9HA1cDZxMjLwsjI0sDBzNDNxDLXxMDYx8jIAKIoEKDHAARwNC-sP1o8BK8JhQkBthkO6oqAgA_JVfXA!!/); (Last accessed Nov. 6, 2019).

Maryland, Plaintiff was injured by the M2a in Maryland, and Plaintiff underwent a painful and invasive revision surgery in Maryland.

15. Venue is proper in United States District Court for the District of Maryland, Northern Division, in that pertinent facts, i.e. revision surgery, giving rise to this suit occurred in City of Germantown, County of Montgomery, which is located in the District of Maryland Northern Division.

16. Suit is brought on behalf of Plaintiff for damages in excess of $75,000.

STATEMENT OF FACTS

A. The Biomet M2a is different than the typical hip replacement

1. A hip replacement surgery replaces the natural head and socket of the hip joint with artificial components.
2. The majority of hip replacements implanted world-wide over the past several decades have utilized a replacement hip joint consisting of a metal head making contact with an ultra-heavy-duty plastic cup inside a metal shell.
3. This typical hip replacement consisting of a metal-plastic interface has been refined to the point that ultra-heavy-duty plastic hip replacements have a greater than 99.5 percent success rate per year.
4. The Biomet M2a instead uses a metal replacement head interfacing directly with a metal shell; there is no plastic liner in the M2a. Accordingly, this type of hip system is commonly referred to as a metal-on-metal hip replacement.

B. Metal-on-metal hip replacements were tried decades ago and abandoned

5. In the 1960s and early 1970s, hip replacement manufacturers first began to market metal-on-metal hip replacements to surgeons.
6. Unfortunately, these early metal-on-metal hip replacements experienced a high rate of

heavy metal poisoning and failure.

7. When the metal shell and metal head of these implants rubbed together, they released toxic cobalt and chromium debris into the body.

8. The cobalt and chromium debris resulted in patients suffering heavy metal poisoning, causing tissue death.

9. As a result, the medical community abandoned metal-on-metal hip replacements due to health and safety concerns in the 1970s.

C. Biomet and the Design Surgeon revived abandoned metal-on-metal hip replacements with M2a

10. Despite the prior failure of metal-on-metal hip replacements to perform as intended, Biomet began designing metal-on-metal hip replacements in the 1990s.

11. The first M2a hip replacement, the M2a Taper, was created and began being sold in the United States in 2001.

    Biomet worked with a design surgeon named Dr. John Cuckler to promote the M2a line, and in return, Dr. Cuckler was paid millions of dollars.

D. Biomet employed a loophole to avoid testing M2a

12. Despite their knowledge that early metal-on-metal hip replacements were a failure and resulted in heavy metal poisoning, Biomet conducted extremely limited testing of the M2a before selling it for implantation into the bodies of patients.

13. To avoid comprehensive testing of the M2a hip replacement, Biomet claimed to United States regulators that the M2a should be "grandfathered-in" because it was substantially similar to hip replacements sold prior to May 28, 1976. [2]

[2] *See,* https://www.accessdata.fda.gov/cdrh_docs/pdf4/K042037.pdf containing Biomet Manufacturing Corp.'s 510(k) Summary of Safety and Effectiveness (Last accessed Nov. 6, 2019).

14. This loophole required no testing for safety or efficacy.

E. Defendants claimed that the M2a was a "lifetime hip" and suitable for use in younger, more active patients

15. Defendants claimed that without the plastic liner to wear out, the Biomet M2a should last a patient's lifetime.

16. Defendants claimed that the Biomet M2a was suitable for implantation in younger, more active patients.

17. Defendants promoted the M2a as a "lifetime hip."

18. Defendants represented that the expected useful safe life of the M2a was well in excess of 20 years.

F. Defendants Fraudulently Misrepresented to The Public by Marketing The M2a As Having "Low Wear"

19. The M2a produces an exponentially larger number of smaller and more toxic wear particles than wear particles produced from plastic hip implants.

20. Biomet had actual knowledge by 2000 that heavy metal poisoning is related to the size and total number of these metal particles as opposed to the total weight of released metal particles. Further, Defendants had actual knowledge that these particles are toxic.

21. Plastic wear particles released from polyethylene implants are much larger and less reactive than heavy metal wear from metal-on-metal implants. Testing protocols for wear in polyethylene implants allows for measurement of the wear by total weight.

22. These same protocols, however, *explicitly* warn against the use of the protocols for measuring wear in metal-on-metal implants, like the M2a. This is, in large part, because the toxicity and reactivity of heavy metal wear is not related to weight, but particle size and count.

23. Biomet knowingly and intentionally conducted laboratory "wear testing" for the M2a

in a way that was *only* designed for testing of plastic hip implants. Particularly, the test protocols only measured wear by total weight.

24. Biomet was fully aware that the M2a produced more toxic wear than polyethylene implants, regardless of total weight comparisons.

25. In fact, in 2003, Dr. Cuckler warned Biomet that they would be sued for their metal-on-metal hip devices due to health and safety concerns.

26. Despite the aforementioned knowledge, Biomet knowingly and intentionally marketed the M2a by claiming that it produced less wear than polyethylene (plastic) hip replacements. Furthermore, Biomet knowingly and intentionally marketed the M2a by falsely associating its deceptively marketed "low wear" properties with safety and efficacy.[3],[4]

27. Defendants provided this false information about the M2a having lower wear to Plaintiff's orthopedic surgeon prior to implant Plaintiff's M2a hip.

28. Plaintiff's surgeon relied on this false information in deciding to use the M2a Hip installed in Plaintiff.

G. Defendants Suppressed Reports of Problems with The M2a And Deceived Surgeons into Believing That Concerns About Heavy Metal Poisoning Were False

29. Defendants knowingly and intentionally spread false information claiming that decades of experience with previous metal-on-metal implants purportedly resulted in zero instances of heavy metal poisoning.[5]

30. Defendants engaged in a knowing and intentional scheme to hide clinical information

[3] *See,* http://www.biomet.com/wps/wcm/connect/internet/acb6d5c6-e3e9-42e2-b3e6-83fd38a567f1/Y-BMT-735_021502_K.pdf?MOD=AJPERES, (Last accessed Nov. 6, 2019).
[4] *See*, http://www.biomet.com/campaign/trueAlternativeBearings/BOI03400MagnumDesignRationale.pdf (Last accessed Nov. 6, 2019).
[5] *See* http://www.grossortho.com/images/stories/pdf/currenttopics/MetalIonWhitePaper.pdf. (Last accessed Nov. 6, 2019).

relating to heavy metal poisoning from its own metal-on-metal hip replacements.

31. This scheme included explicit training to Biomet's sales representatives on how to deceptively convince surgeons that reports of heavy metal poisoning were all fake; merely a theoretical concern; and a scheme by competitors who do not sell metal-on-metal hip replacements to steal business.

32. The information that the Biomet Defendants provided about Biomet hip replacement systems far exceeded the information provided on M2a packaging or labeling.

33. At all times relevant to this Complaint, Plaintiff's surgeon relied upon information provided by the Biomet Defendants in selecting the M2a hip replacement for implantation into Plaintiff's body.

34. Prior to initial implantation, Plaintiff, Julia Brooks was informed by her surgeon that the M2a hip implant was the best product available on the market; that given her age at the time of implant, a MoM implant would be best given its longevity compared to other articulations, and that such longevity could be up to a lifetime of the patient. Plaintiff relied upon her doctor's knowledge and expertise in moving forward with implantation of the M2a. Had Plaintiff known of the issues regarding M2a hips discussed herein, Plaintiff would not have proceeded with implantation of the M2a product.

35. Biomet Defendants, due to their sales representatives' role in the sale of particular implant components to orthopedic surgeons, have notice of every surgery in which Biomet components are implanted. This includes surgeries in which Biomet components are used to replace failed M2a implants. As a result, Biomet Defendants possess a unique set of clinical information through which the success or failure of their

implants can be analyzed.

36. Unfortunately, Biomet Defendants engaged in a corporate practice of under reporting and failing to properly analyze clinical information in their possession regarding implants which they sell.

37. In 2016 and 2018 this practice resulted in multiple "483" observations by the FDA regarding Biomet Defendants' failure to properly handle complaint reports and failure to properly analyze clinical information regarding product failures. Zimmer Biomet was aware of these observations and responded to the FDA on Zimmer Biomet letterhead.

38. Biomet Defendants also marketed their metal-on-metal hip replacements based upon what it claimed was a low "reported adverse event rate" of ".056". However, Biomet Defendants were intentionally and knowingly failing to include large numbers of adverse events, especially those relating to heavy metal poisoning. Biomet was fully aware that this scheme artificially suppressed the "reported adverse event rate." Regardless, Biomet consistently used the figure in its marketing. Biomet was aware that this figure would be heavily relied upon by the medical community.

H. Biomet falsely claimed it conducted extensive testing of M2a

39. Despite the fact that Biomet conducted no clinical testing of the M2a hip replacement, it has continuously claimed "[t]he M2a-Magnum™ Large Metal Articulation System offers optimal joint mechanic restoration and ultra-low-wear rates in vivo" citing to a 1996 article about previously abandoned types of metal-on-metal hip replacements.[6]

40. Biomet also stated that "once the manufacturing process is complete, *all* M2a-Magnum

[6] *See*, http://www.biomet.com/campaign/trueAlternativeBearings/BOI03400MagnumDesignRationale.pdf (Last accessed Nov. 6, 2019).

components undergo a thorough inspection process to ensure precise manufacturing tolerances have been achieved. Major dimensions such as sphericity (roundness) *and* roughness are verified using non-contacting light interferometry through the use of ZygoPCI Laser. The M2a-Magnum™ articulation is manufactured to a 5 micron deviation, compared to the ISO standard of 10 microns. Roughness (Ra value) is a measure of the texture of a surface quantified by vertical deviations. All M2a-Magnum™ components are tested to ensure that the Ra value does not exceed .005 microns. **These key measurements are necessary to maintain low wear and optimal clearance** found in M2a-Magnum™ components." (Internal cross references omitted; emphasis added).[7]

41. However, when forced to confront these claims, Biomet Staff Engineer, Malcolm Naylor, issued a public declaration on November 1, 2019 admitting the untruthfulness of those claims: "Biomet did not use the Zygo to test and/or the M2a cups and heads for surface finish measurements, not to ensure that the M2a cups and heads met the surface finish specification designed and/or adopted by Biomet for the M2a cups and heads."

42. In a 2004 publication titled "Metal Ions – A Scientific Review," Biomet falsely concludes that: "Extensive research and years of clinical trials have failed to prove any cause for concern associated with the ion levels exhibited from metal-on-metal implants."[8]

43. In fact, in a heading on page 7 of the publication, Biomet goes so far as to claim that:

[7] *Id.*
[8] *See* http://www.grossortho.com/images/stories/pdf/currenttopics/MetalIonWhitePaper.pdf. (Last accessed Nov. 6, 2019).

"Cobalt and Chromium may be beneficial to the body as established by research and listed by the US government."[9]

44. The 2004 publication by "Biomet Orthopedics, Inc., the Most Responsive Company in Orthopedics," is still available to orthopedic surgeons and the public online today at http://www.grossortho.com/images/stories/pdf/currenttopics/MetalIonWhitePaper.pdf (Last accessed November 6, 2019).

I. Dr. Cuckler conducted secret M2a marketing campaign in exchange for millions of dollars

45. In conjunction with the promotion of the M2a hip replacement, the one of the Biomet Defendant's "design surgeons," gave speeches and published articles such as "The Rationale for Metal-on-Metal Total Hip Arthroplasty" published in 2005, claiming that there were "no adverse physiologic effects" to metal-on-metal hip replacements.

46. At the time that the design surgeon published the above article, Biomet was paying Dr. Cuckler percentage of the sale price of M2a metal-on-metal hip replacement systems sold in the United States.

47. Pursuant to a Deferred Prosecution Agreement with the Department of Justice, in 2008, Biomet made public that Dr. Cuckler received payments from Biomet of between $3.0 and $3.1 million dollars in just the previous year. Extrapolating the one year that Biomet's payments to the design surgeon are publicly available, leads to the conclusion that the Dr. Cuckler has received tens of millions of dollars from Biomet

J. Thousands of M2a hip replacements are implanted in Maryland and Ohio citizens

48. Defendants' promotion of the M2a hip replacement was extremely successful.

[9] *Id.*

49. In Maryland alone, thousands of M2a metal-on-metal hip replacements were sold by Defendants and surgically implanted into the bodies of patients.

50. These hip replacements implanted in Maryland citizens were designed by Biomet; promoted by Biomet; sold by Biomet; and implantation and follow-up instruction were provided to surgeons by Biomet.

K. Defendants continue to claim that the M2a is safe and successful

51. Biomet Defendants sold M2a hip replacements for implantation into the bodies of patients up to the year 2014 or 2015.

52. Biomet Defendants ceased selling Biomet M2a metal-on-metal hip replacement in 2014 or 2015.

53. However, Zimmer Biomet, who wholly owns Defendants, have continued to reassure surgeons and the public that the heavy metal poisoning seen with other metal-on-metal hip replacements is not an issue with the M2a.

54. To this day, Zimmer Biomet continues to claim to orthopedic surgeons and the public that the M2a is a safe and successful product.

L. In 2010 Johnson & Johnson voluntarily recalled almost identical hip replacement

55. Approximately the same time as Defendants began selling the M2a, Johnson & Johnson began selling the DePuy ASR.

56. The DePuy ASR was almost identical to the M2a in its primary design features.

57. Like the M2a, the DePuy ASR was a monoblock metal-on-metal hip replacement system with its cobalt chromium alloy head articulating against its cobalt chromium alloy shell.

58. In the summer of 2010, in response to "higher than expected revision rates," Johnson & Johnson conducted a world-wide recall of the DePuy ASR hip replacement.

59. Johnson & Johnson advised surgeons to conduct detailed testing and follow-up of patients with DePuy ASR hip replacements.

60. As a result of the testing and follow-up, dangerously high heavy metal levels were discovered in a significant percentage of patients necessitating surgery to remove the metal-on-metal hip replacements.

61. Heavy metal poisoning and tissue death from the toxic heavy metals released by the ASR was widely reported in the medical literature.

62. The Defendants were aware of the reports and studies discussing the injuries suffered by metal-on-metal patients as a result of this very similar product.

M. <u>Defendants' response to the recall of the almost identical product: Sell more M2as!</u>

63. In response to the 2010 voluntary world-wide recall of an almost identical hip replacement, Defendants did not:

    a. Recall Defendants' almost identical M2a hip replacement.
    b. Suspend sales of their almost identical hip replacement pending a full investigation.
    c. Conduct comprehensive testing of the M2a to ensure it was not prone to causing heavy metal poisoning.
    d. Warn surgeons of the design similarities and the need to inform and carefully follow-up their patients.

64. Instead, Defendants increased promotion of M2a, attempting to capture market share lost by Johnson & Johnson due to its voluntary recall.

65. Defendants devised marketing strategies to differentiate the M2a from the recalled ASR hip replacement and other metal-on-metal hip replacements.

66. Defendants promoted these marketing strategies to surgeons and the public to reassure them that the M2a did not cause heavy metal poisoning.

N. In 2010, Netherlands hospital warns Biomet of high rate of pseudotumors with M2a

67. At the same time that Defendants were reassuring orthopedic surgeons and the public of the safety of the M2a, they were receiving reports of just the opposite.

68. Isala Klinieken ("Isala") located in Zwolle, The Netherlands, has historically had a long and close relationship with Biomet.

69. Isala was in fact a Biomet funded study site.

70. Prior to 2007, Isala implanted patients with Biomet M2a metal-on-metal hip replacements.

71. In 2010, Isala reported to Biomet that when it performed CT scans of over 100 patients' hips, more than a third had pseudotumors adjacent to the M2a hip replacement.

O. Biomet was warned that CT/MRI scanning was necessary to see tissue death from M2a heavy metal poisoning

72. Isala reported to Biomet that the necessity for revision surgery was not identified until Isala conducted the CT scanning of their M2a patients.

73. Isala warned that by the time that swelling, pain, and clicking indicating tissue death resulting from the heavy metal poisoning became apparent, the patient may have already suffered extensive injury.

74. In 2010, Isala informed Biomet that it had ceased implanting Biomet M2a hip replacements in its patients.

75. Isala encouraged Biomet to adopt a comprehensive screening protocol using CT and MRIs of all patients with Biomet M2as implanted in their bodies and warned that without such an enhanced protocol, patients may be at risk.

76. The Isala Klinieken reported some of its finding regarding the M2a in a British medical

journal.[10]

77. Despite all of these critical warnings provided by the Isala Klinieken, Defendants failed to inform surgeons or patients of the study, ignored the need for follow-up screening, and instead continued to promote the M2a for implantation into the bodies of patients.

P. Finland University reports severe adverse reactions from M2a heavy metal debris

78. Likewise, Turku University in Turku, Finland has historically had a long and close relationship with Biomet.

79. Like Isala, Turku University was a Biomet funded study site.

80. From 2005 to 2012, the Biomet M2a metal-on-metal hip replacement was the most commonly implanted hip replacement at Turku University.

81. In 2013, Turku University reported to Biomet that when the University examined a sample of their patients implanted with the M2a, over half of the patients were experiencing ARMD or "Adverse Reaction to Metal Debris" from the M2a.

82. MRIs of the sample of Turku University M2a patients revealed that over half had a psuedotumor or fluid collection in their hip.

83. Despite its long and close relationship with Biomet, in a 2013 publication of the Nordic Orthopedic Federation, Turku University stated that "ARMD is common after … M2a total hip arthroplasty, and we discourage the use of this device." [11]

84. Defendants failed to inform surgeons or patients of this study, that Turku University had discouraged use of the M2a, the need for surgeons to screen their patients for

[10] Bosker B, Ettema H, Boomsma M, et al. High incidence of pseudotumour formation after large-diameter metal-on-metal total hip replacement: a prospective cohort study. *J Bone Joint Surg Br.* 2012 Jun;94(6):755-61.

[11] Mokka J, Junnila M, Seppänen M, et al. Adverse reaction to metal debris after ReCap-MAGNUM-Magnum large-diameter-head metal-on-metal total hip arthroplasty. *Acta Orthopaedica*. 2013;84(6):549-554.

Adverse Reaction to Metal Debris, and instead continued to promote the M2a for implantation into the bodies of patients.

Q. Biomet used Olympic gymnast Mary Lou Retton as M2a spokesperson

85. As part of the promotion of the M2a hip replacement, Biomet hired Olympic gold-medal gymnast, Mary Lou Retton, as a spokesperson.

86. Mary Lou Retton had received a M2a hip replacement in the mid-2000's.

87. Biomet heavily promoted to surgeons and the public that the M2a hip allowed "younger, more active patients, like Mary Lou" to "return to her normal activities, including her workout schedule."[12]

88. Mary Lou Retton was used by Defendants to promote the M2a in brochures, in newspapers, on radio and television, and in-person to orthopedic surgeons and the public. [13]

89. A heading on Biomet's website proclaims, "Mary Lou lives pain-free, and so should you."[14]

R. Mary Lou Retton has sued Biomet over defective M2a hip replacement

90. Unfortunately, Mary Lou Retton, like the Plaintiff in this action, is a M2a victim.

91. While initially "pain-free," Mary Lou Retton suffered heavy metal poisoning from the M2a hip replacement necessitating the surgical removal and replacement of the metal-on-metal hip replacement.

92. Mary Lou Retton was so severely injured by the M2a metal-on-metal hip replacement,

[12] *See*, http://www.biomet.com/fileLibrary/Patient_Education/PatientEdBrochures/Hip/English/Mary%20Lou%20Retton%20-%20Magnum%20Magnum.pdf (Last accessed Nov. 6, 2019).
[13] *See*, http://www.biomet.com/news/getFile.cfm?id=113&rt=inline&type=pr (Last accessed Nov. 6, 2019).
[14] *See*, http://www.biomet.com/fileLibrary/Patient_Education/PatientEdBrochures/Hip/English/Mary%20Lou%20Retton%20-%20Magnum%20Magnum.pdf (Last accessed Nov. 6, 2019).

that despite her status as a celebrity spokesperson for the product, she too sued the company.

S. Despite knowing of the failure of the M2a in Mary Lou Retton for years, Biomet continues to claim her a success story

93. Defendants failed to inform surgeons and the public that Mary Lou Retton suffered heavy metal poisoning and had to have her M2a surgically removed.

94. Defendants continue to cite to Mary Lou Retton as a patient success story.

95. Biomet has known of the failure of Mary Lou Retton's hip replacement for years but has continued to promote to surgeons and the public a false story.

T. Australian government required Biomet to recall M2a

96. Australia has a world-leading implant registry which keeps track of every orthopedic hip replacement sold, implanted, and replaced in Australia.

97. Biomet ceased selling the M2a in Australia in 2011.

98. In 2014, the Australian government communicated to Biomet that it was seeing excessive failure rates of the M2a in Australian patients.

99. In 2015, Biomet, "in consultation with" the Australian government issued a "Hazard Alert" recalling the Biomet M2a due to a "higher than expected revision rate."

100. Because Biomet had already ceased selling the M2a in Australia, the Australian government's recall of the M2a consisted of the "Hazard Alert" and mandating Biomet notify implanting surgeons in Australia of the recall and excessive revision rate.

101. On information and belief, Defendants were conducting due diligence in its merger with Biomet, Inc. on or about the time that the Australian Hazard Alert was issued.

102. On information and belief, Defendants were aware of the Australian Hazard Alert prior to the completion of the merger with Biomet, Inc.

103. Defendants have failed to disclose to orthopedic surgeons or the public that the M2a hip replacement was recalled in Australia and that the Australian government issued a "Hazard Alert" regarding the M2a.

U. Defendants recalled M2a in various European Union countries

104. Biomet Defendants ceased selling the M2a implants in Europe in December 2012.

105. In 2016, Defendants, after discussion with regulatory agencies, issued a Field Safety Corrective Action based on "data collected by the National Joint Register (NJR) for England, Wales and Northern Ireland which revealed that this hip system has a higher than expected revision rate."

106. Because Biomet had already ceased selling the M2a in Europe, the recall consisted of the "Urgent Field Safety Notice" and notification to implanting surgeons of the recall, the excessive revision rate, and guidance for patient follow up.

107. Defendants have failed to disclose to orthopedic physicians or the public that the M2a hip replacement had been recalled in Europe and that the a "Urgent Field Safety Notice" was issued in various European countries.

V. Since 2012 Biomet has had false M2a failure rate data posted on its website

108. From 2012 until today, Biomet had posted on its website under the heading "Important information regarding metal-on-metal hips" data purporting to show the success of Biomet's metal-on-metal hip replacements at http://www.biomet.com/wps/portal/internet/Biomet/Healthcare-Professionals/products/orthopedics/important-information-mom-hips (Last accessed November 6, 2019.).

109. The "Important information regarding metal-on-metal hips" is clearly intended to reassure patients and surgeons that Biomet's metal-on-metal hip replacements are safe and performing as intended.

110. The "Important information regarding metal-on-metal hips" states "Biomet has been closely monitoring the available data regarding its [metal-on-metal] hip devices."

111. The "Important information regarding metal-on-metal hips" claims that there is no statistically significant difference between survivorship of the Biomet Magnum and the Biomet M2a-38 and hip replacements generally in the Australian National Joint Registry and the England and Wales National Joint Registry.

112. By 2015, at the latest, Biomet was aware, and on information and belief Zimmer Biomet Holdings was aware, that the Biomet Magnum and M2a-38 were failing at a statically significantly higher rate than hip replacements generally in the Australian National Joint Registry.

113. Likewise, for years Biomet has been aware that the Magnum and M2a-38 were failing at a significantly significant higher rate in the England and Wales National Joint Registry than hip replacements generally.

114. Despite knowing that it would mislead orthopedic surgeons and the public concerning the safety of its metal-on-metal hip replacements, Biomet has continued to promote false information regarding the safety of its M2a hip replacement.

W. The Biomet metal-on-metal hips are a ticking time-bomb implanted in thousands of Maryland citizens' bodies

115. The Biomet M2a is inherently defective.

116. When implanted in patients, it is prone to release toxic levels of cobalt and

chromium.

117. Patients thus can suffer injury including but not limited to: heavy metal poisoning, elevated levels of cobalt and chromium in the blood, pseudotumors, tissue necrosis, osteolysis, muscle wasting, cold-welding, loosening of the acetabular component, delamination of the acetabular component, corrosion related injury, and other severe injuries.

118. All Defendants are continuing to fail to warn surgeons and patients that the M2a metal-on-metal hip replacements that were surgically implanted in patients' bodies may be releasing toxic heavy metals has left thousands of patients with ticking time-bombs in their hips.

119. Based on the studies discussed above and others, hundreds, if not thousands, of patients have already suffered undiagnosed pseudotumors, tissue death, bone death, etc. as a result of poisoning from the toxic heavy metals released from the M2a.

X. Maryland is facing a public health disaster from unmonitored M2as

120. As a result of Defendants' failure to warn surgeons and patients of the necessity for immediate testing and screening of implanted M2a hip replacements, the number of patients poisoned and severely injured by the M2a will greatly increase.

121. The State of Maryland are facing a public health disaster from unmonitored M2a metal-on-metal hip replacements.

Y. Plaintiff suffered heavy metal poisoning from M2a

122. The Plaintiff was implanted with the M2a Magnum hip replacement and suffered heavy metal poisoning, tissue death, and pain.

123. As a result of the heavy metal poisoning by the Biomet M2a, Plaintiff had to

undergo an additional surgical procedure to surgically remove the defective hip replacement and replace it with one with a heavy-duty plastic liner.

124. Plaintiff then had to undergo an extensive recovery and rehabilitation.

125. As a result, Plaintiff lost mobility, needlessly suffered severe pain, was forced to undergo unnecessary revision surgeries, surgical trauma, and extensive rehabilitation.

Z. Julia Brooks underwent a painful revision surgery for their failed left total hip arthroplasty

126. Julia Brooks was implanted with the M2a Magnum system into their left hip on September 23, 2008. Plaintiff was 48 years old at the time and looked forward to continuing an active lifestyle.

127. Before the surgery, Julia Brooks met with her surgeon. During the pre-surgical discussion, Plaintiff's surgeon recommended the M2a metal-on-metal bearing technology, relying on Biomet's representations that the product featured superior longevity and reduced wear. During the meeting, Plaintiff's surgeon indicated that the Biomet metal-on-metal product was ideal for Plaintiff because it would not wear out and it was not likely there would be a need to undergo a second surgery later in life. As a result, Plaintiff elected to proceed with the Biomet product.

128. Julia Brooks was not aware that the Biomet product had not been clinically tested for safety and efficacy by Biomet before being released to the market.

129. Julia Brooks was not informed about the surprising lack of clinical awareness regarding the risks of metal ion wear presented by the Biomet metal-on-metal product.

130. Julia Brooks was not aware of the serious concerns raised by those responsible for understanding the clinical safety of metal-on-metal bearings, including the unresolved concerns raised by members of the August 2001 FDA panel responsible for the pre-

clinical review of metal-on-metal hip products.

131. Julia Brooks was not aware that Biomet had entered into unethical financial arrangements for the promotion of metal-on-metal hip implants, leading to criminal charges and, eventually, Deferred Prosecution Agreements.

132. Julia Brooks was not aware of serious breakdowns in Biomet's adverse event reporting systems, which were necessary to accurately track the safety and performance of the Magnum product.

133. Plaintiff's surgeon, Dr. Marc Brassard implanted Julia Brooks left Biomet hip products in excellent position, performing the surgery at Anne Arundel Medical Center in Annapolis, Maryland.

134. Despite Plaintiff's surgeon's excellent positioning of the M2a products, Julia Brooks later developed problems associated with metallosis.

135. On February 3, 2020, Dr. Tariq Nayfeh surgically removed and replaced the failed left M2a hip product, duet to metallosis from the metal prosthesis. Upon surgically opening Julia Brooks hip area, Plaintiff's surgeon encountered a pseudotumor, metal tissue staining, and inflammatory tissue.

136. Plaintiff was not aware and could not, with the exercise of reasonable diligence, have discovered he was injured, that the M2a implanted into her was defective, and/or that she was injured by the defective M2a implanted into him until February 3, 2020.

137. Dr. Neyfeh removed the entire Biomet M2a metal-on-metal prosthesis and articulating construct, except for the femoral component, and replaced it with an alternative non-metal-on-metal construct.

138. Julia Brooks has undergone a long and painful recovery and rehabilitation from the

surgical revision of the failed left Biomet M2a hip implant which has affected her quality of life.

DAMAGES AND CAUSES OF ACTION

1. As a direct and proximate result of the defective M2a hip replacement, Plaintiff suffered injuries, including but not limited to economic injury, significant pain, tissue destruction, metal wear, metal poisoning, loss of enjoyment of life, and limitation of daily activities.
2. Plaintiff expects to continue suffering such injuries in the future as a result of the injuries received from the M2a.
3. As a direct and proximate result of the defective M2a, Plaintiff incurred medical expenses and expects to incur additional medical expenses in the future.
4. As a direct and proximate result of the defective M2a, Plaintiff incurred lost earning potential, income and earnings.
5. As a direct and proximate result of the defective M2a, Plaintiff experienced emotional trauma and distress and is likely to experience emotional trauma and distress in the future.
6. A jury previously found that Biomet's conduct with regard to the M2a Magnum was willful and wanton by a preponderance of clear, convincing, and satisfactory evidence," and the 8th Circuit affirmed that it was reasonable for a jury to reach that conclusion.

COUNT I
STRICT LIABILITY: DESIGN DEFECT
(Against all Defendants)

1. Plaintiff incorporates by reference and re-alleges each paragraph set forth above.
2. Prior to Plaintiff's hip replacement surgery and at all relevant times, Defendants designed, distributed, manufactured, sold and marketed the M2a Hip System for

implantation into consumers, such as Plaintiff.

3. The M2a Hip System components implanted in Plaintiff contained design defects making the product unreasonably dangerous. Such unnecessary risks and defects include but are not limited to, the M2a Hip System's acetabular cup had a tendency to detach, disconnect, and/or loosen from a patient's acetabulum, and cause pain, inhibit movement and require revision surgery. Said defects also include the fact that the clearance between the M2a Hip System's acetabular cup and femoral head are less than called for in design specifications, resulting in excessive wear and causing the M2a Hip System to generate dangerous and harmful levels of toxic metal debris in the patient's body.
4. Plaintiff's physicians employed the M2a Hip System in the manner in which the M2a Hip System was intended to be used, making such use reasonably foreseeable to Defendants.
5. As a direct and legal result of Defendants' design, manufacture, marketing and sale of the M2a Hip System, Plaintiff suffered the injuries herein described.
6. Defective design and manufacture, and marketing and sale of the M2a Hip Systems that was implanted in Plaintiff was a substantial factor in causing Plaintiff's injuries, as described herein.
7. As a direct and legal result of Defendants' design, manufacture, marketing and sale of the M2a Hip System, Plaintiff suffered the herein described injuries, including pain and elevated metal ion debris, revision surgery, and other injuries presently unknown.
8. As a direct and legal result of Defendants' design, manufacture, marketing and sale of the M2a Hip System, it became necessary for Plaintiff to incur expenses for doctors,

hospitals, surgeries, nurses and other reasonably required and medically necessary supplies and services, which are still continuing.

9. As a direct and legal result of Defendants' design, manufacture, marketing and sale of the M2a Hip System, Plaintiff was implanted with a defective M2a Hip System and has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

COUNT II
STRICT LIABILITY: FAILURE TO WARN
(Against all Defendants)

10. Plaintiff incorporates by reference and re-alleges each paragraph set forth above.

11. Prior to Plaintiff's initial hip replacement surgery and at all relevant times, Defendants designed, manufactured, marketed, distributed, and sold the M2a Hip System for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States.

12. The M2a Hip System had potential risks and side effects that were known or knowable to Defendants by the use of scientific knowledge available at and after the time of manufacture, marketing, distribution and sale of the M2a Hip System that was implanted in Plaintiff. Defendants knew or should have known of the defective condition, characteristics and risks associated with said product, as previously set forth herein.

13. The M2a Hip System that was designed, manufactured, marketed, distributed and sold by Defendants and implanted in Plaintiff was in a defective condition that was unreasonably and substantially dangerous to ordinary patients, such as Plaintiff. Ordinary patients and their physicians, including Plaintiff and Plaintiff's physicians,

would not and could not have recognized or discovered the potential risks and side effects of the M2a Hip System as set forth herein.

14. The warnings and directions provided with the M2a Hip System by Defendants failed to adequately warn of the potential risks and side effects of the M2a Hip System and the dangerous propensities of said medical device, which risks were known or were reasonably scientifically knowable to Defendants.

15. The warnings to Plaintiff and Plaintiff's implanting physicians about the dangers the M2a Hip System posed to patients were inadequate. Examples of the inadequacy of Defendants' warnings include, but are not limited to, one or more of the following particulars:

    a. The M2a Hip System warnings were insufficient to alert Plaintiff and Plaintiff's physicians as to the risk, scope, duration and severity of adverse events and/or reactions associated with the M2a Hip System, subjecting Plaintiff to risks which exceeded the benefits of the M2a Hip System;

    b. Defendants sold the M2a Hip System using misleading material emphasizing the efficacy of the M2a Hip System while downplaying the risks associated with it thereby making use of the M2a Hip System more dangerous than the ordinary patient and physician would expect;

    c. Defendants failed to disclose that the M2a Hip System was inadequately tested;

    d. Defendants failed to convey adequate post-marketing warnings regarding the risk, severity scope and/or duration of the dangers posed by the M2a Hip System; and

    e. Defendants failed to provide physicians, including Plaintiff's physicians, with information and instructions sufficient to avoid or mitigate the M2a Hip System's dangers.

16. Defendants' M2a Hip System components were expected to and did reach Plaintiff and Plaintiff's physicians without substantial change in their condition as designed, manufactured, distributed and sold by Defendants. Additionally, Plaintiff's physicians

used the M2a Hip System in the manner in which the M2a Hip System was intended to be used, making such use reasonably foreseeable to Defendants.

17. As a direct and legal result of Defendants' manufacture, marketing, distribution and sale of the M2a Hip System, Plaintiff was implanted with a M2a Hip System and have suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

18. Defendants' lack of sufficient instructions or warnings prior to and after the date of Plaintiff's M2a Hip System hip replacement surgery was a substantial factor in causing Plaintiff's injuries and damages, as described herein.

COUNT III
NEGLIGENCE: DESIGN DEFECT
(Against all Defendants)

19. Plaintiff incorporates by reference and re-alleges each paragraph set forth above.

20. Defendants had a duty to exercise reasonable care in the design of the M2a Hip System. In particular, they had a duty to assure that their products did not pose an unreasonable risk of bodily harm and adverse events due to the design.

21. Defendants failed to exercise reasonable care in the design and formulation of the M2a Hip System in that they knew or should have known that the M2a Hip System could cause significant bodily harm and was not safe for use by consumers.

22. Defendants' negligence in designing the M2a Hip System includes but is not limited to the fact that the M2a Hip System was negligently designed and manufactured creating increased metal wear and corrosion.

23. At all relevant times, it was foreseeable to Defendants that patients like Plaintiff would suffer injury as a result of Defendants' failure to exercise ordinary care as described

above.

24. As a direct and legal result of Defendants' negligence, Plaintiff has suffered physical injuries, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

25. Defendants' negligence in designing the M2a Hip System was prior to the date of Plaintiff's M2a Hip System hip replacement surgery and was a substantial factor in causing Plaintiff's injuries and damages, as described herein.

COUNT IV
NEGLIGENCE: FAILURE TO WARN
AND NEGLIGENT MARKETING
(Against all Defendants)

26. Plaintiff incorporates by reference and re-alleges each paragraph set forth above.

27. Defendants had a duty to exercise reasonable care in providing adequate warnings to physicians and in marketing the M2a Hip System to physicians.

28. Defendants failed to exercise reasonable care in warning physicians about the unique risks associated with the M2a Hip System such as metallosis, elevated metal ion levels, and tissue destruction and in marketing the M2a Hip System to physicians and patients.

29. At all relevant times, it was foreseeable to Defendants that patients like Plaintiff would suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

30. As a direct and legal result of Defendants' negligence, Plaintiff has suffered physical injuries, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

31. Defendants' negligence in failing to warn the M2a Hip System and in marketing the M2a Hip System was prior to the date of Plaintiff's M2a Hip System hip replacement

surgery and was a substantial factor in causing Plaintiff's injuries and damages, as described herein.

COUNT V
STRICT LIABILITY: MANUFACTURING DEFECT
(against all Defendants)

32. Plaintiff incorporates by reference and re-alleges each paragraph set forth above.

33. Prior to Plaintiff's hip replacement surgery and at all relevant times, Defendants designed, distributed, manufactured, sold, and marketed the M2a Hip System for implantation into consumers, such as Plaintiff.

34. The M2a Hip System components implanted in Plaintiff contained manufacturing defects making the product unreasonably dangerous. Such unnecessary risks and defects include but are not limited to, failing to test and maintain clearance according to design protocols.

35. Plaintiff's physicians employed the M2a Hip System in the manner in which the M2a Hip System was intended to be used, making such use reasonably foreseeable to Defendants.

36. As a direct and legal result of Defendants' manufacture of the M2a Hip System, Plaintiff suffered the injuries herein described.

37. Defective manufacture and sale of the M2a Hip Systems that was implanted in Plaintiff was a substantial factor in causing Plaintiff's injuries, as described herein.

38. As a direct and legal result of Defendants' manufacture and sale of the M2a Hip System, Plaintiff suffered the herein described injuries, including pain and elevated metal ion debris, revision surgery, and other injuries presently unknown.

39. As a direct and legal result of Defendants' manufacture and sale of the M2a Hip

System, it became necessary for Plaintiff to incur expenses for doctors, hospitals, surgeries, nurses and other reasonably required and medically necessary supplies and services, which are still continuing.

40. As a direct and legal result of Defendants' design, manufacture, marketing and sale of the M2a Hip System, Plaintiff was implanted with a defective M2a Hip System and has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

COUNT VI
NEGLIGENCE: MANUFACTURING DEFECT
(against all Defendants)

41. Plaintiff incorporates by reference and re-alleges each paragraph set forth above.

42. Defendants had a duty to exercise reasonable care in the manufacture of the M2a Hip System. In particular, they had a duty to assure that their products did not pose an unreasonable risk of bodily harm and adverse events due to the manufacture

43. Defendants failed to exercise reasonable care in the manufacturing of the M2a Hip System in that they knew or should have known that the M2a Hip System could cause significant bodily harm and was not safe for use by consumers.

44. Defendants' negligence in manufacturing the M2a Hip System includes but is not limited to the fact that the M2a Hip System was negligently manufactured creating increased metal wear and corrosion.

45. At all relevant times, it was foreseeable to Defendants that patients like Plaintiff would suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

46. As a direct and legal result of Defendants' negligence, Plaintiff has suffered physical

injuries, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

47. Defendants' negligence in manufacturing the M2a Hip System was prior to the date of Plaintiff's M2a Hip System hip replacement surgery and was a substantial factor in causing Plaintiff's injuries and damages, as described herein.

COUNT VII
BREACH OF EXPRESS WARRANTY
(Against all Defendants)

Plaintiff incorporates by reference and re-alleges each paragraph set forth above.

48. At all times herein mentioned, Defendants expressly warranted to Plaintiff and Plaintiff's physicians, by and through statements made by Defendants, or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the aforementioned M2a Hip System was safe, effective, fit and proper for its intended use.

49. In utilizing the M2a Hip System, Plaintiff and Plaintiff's physicians relied on the skill, judgment, representations and foregoing express warranties of Defendants.

50. Said warranties and representations were false in that the M2a Hip Systems were not safe and were unfit for the uses for which they were intended.

51. As a result of the foregoing breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

COUNT VIII
BREACH OF IMPLIED WARRANTY
(Against all Defendants)

Plaintiff incorporates by reference and re-alleges each paragraph set forth above.

52. Prior to the time that the M2a Hip System was used by Plaintiff, Defendants impliedly warranted to Plaintiff and Plaintiff's physicians that the M2a Hip System was of merchantable quality and safe and fit for the use for which it was intended. Plaintiff and Plaintiff's physicians were and are unskilled in the research, design and manufacture of the M2a Hip System, and they reasonably relied entirely on the skill, judgment and implied warranty of Defendants in using the M2a Hip System.

53. The M2a Hip System was neither safe for its intended use nor of merchantable quality as warranted by Defendants in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user.

54. Defendants, by selling, delivering and/or distributing the defective M2a Hip System to Plaintiff, breached the implied warranty of merchantability and fitness and caused Plaintiff to suffer severe pain and emotional distress, incur medical expenses and incur a loss of earning capacity.

55. As a result of the aforementioned breach of implied warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

COUNT IX
FRAUDULENT CONCEALMENT
(Against all Defendants)

Plaintiff incorporates by reference and re-alleges each paragraph set forth above.

56. Defendants omitted, suppressed and/or concealed material facts concerning the dangers and risks associated with the use of the M2a Hip System.

57. Further, Defendants purposely downplayed and understated the serious nature of the risks associated with use of the M2a Hip System in order to increase and sustain sales.

58. Defendants had a duty to disclose that the M2a Hip System was not safe for use in

patients and posed an unacceptably high rate of failure and release of metal ion debris.

59. The fact that Defendants omitted, suppressed and concealed was material to consumers and their physicians, and, in particular, to Plaintiff and Plaintiff's physicians' decision to implant M2a Hip Systems in Plaintiff.

60. Defendants had superior knowledge of the facts that they omitted, suppressed and concealed.

61. Defendants omitted, suppressed and concealed material facts, as set forth above, while making false, misleading and partial representations regarding the M2a Hip System.

62. Defendants actively concealed material facts, as set forth above, by continuing to market and sell M2a Hip System hip implants despite their knowledge that the M2a Hip System hip implants are defective and pose serious risk of injury. In response to reports of high incidence of failure of the M2a Hip System hip implants, Defendants purposely downplayed and understated the serious nature of the risks associated with use of the M2a Hip System in order to increase and sustain sales.

63. Plaintiff and Plaintiff's physicians did not know, and could not have learned of the facts that the Defendants omitted and suppressed.

64. Defendants' omission, suppression and concealment of material facts, as set forth above, induced reasonable and justifiable reliance by Plaintiff and Plaintiff's healthcare providers in that Plaintiff and Plaintiff's healthcare providers made the decision to use a M2a Hip System hip implant without the knowledge of said material facts. Instead, Plaintiff and Plaintiff's healthcare providers reasonably and justifiably relied on the Defendants' representations that the M2a Hip System was safe for use and that Defendants' labeling, marketing and promotional materials fully described all known

risks associated with the product. Had Plaintiff and Plaintiff's healthcare providers known that the M2a Hip System was not safe and posed an unacceptably high rate of failure and release of metal ion debris, Plaintiff would not have had a M2a Hip System implanted.

65. As a direct and legal result of Defendants' concealment of material facts, Plaintiff was implanted with an M2a hip System and have suffered physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

66. The foregoing acts, conduct and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive and fraudulent, and were done with a conscious disregard for the health, safety and rights of Plaintiff and other users of Defendants' M2a Hip System, and for the primary purpose of increasing Defendants' profits. As such, Plaintiff is entitled to exemplary damages.

COUNT X
PUNITIVE DAMAGES
(against all Defendants)

Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint and further alleges:

67. Plaintiff is entitled to punitive damages because the Defendants' wrongful acts and/or omissions were wanton or in conscious disregard of the rights of others. Defendants misled both the medical community and the public at large, including Plaintiff, by making false representations about the safety and efficacy of the M2a Hip System and by failing to provide adequate instructions and training concerning its use.

68. Defendants downplayed, understated, and/or disregarded their knowledge of the

serious and permanent side effects and risks associated with the use of the M2a Hip System despite available information demonstrating that the M2a Hip System could loosen and separate, causing serious harm to patients. Such risks and adverse effects could easily have been avoided had Defendant not concealed knowledge of the serious risks associated with the M2a Hip System or provided proper training and instruction to physicians regarding use of the M2a Hip System.

69. Defendants were or should have been in possession of evidence demonstrating that the M2a Hip System caused serious side effects. Nevertheless, Defendants continued to market the M2a Hip System by providing false and misleading information with regard to its safety and efficacy.

70. Defendants' actions were malicious, knowing, vexatious, and willfully harmful to the public.

WHEREFORE, Plaintiff prays for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to, pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;
2. Past and future medical expenses, income, and other economic damages in an amount to be determined at trial of this action;
3. Punitive damages in an amount to be determined at trial of this action;
4. Pre- and post-judgment interest;
5. Attorneys' fees, expenses, and costs; and
6. Such further relief as this Court deems necessary, just, and proper.

Dated: October 20, 2022

/s/ Stephen G. Skinner
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-and-

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-and-

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-and-

BIOMET U.S. RECONSTRUCTION, LLC
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